

Centers for Medicare & Medicaid Services, HHS

§ 482.61

(3) The hospital does not have in effect a 24-hour nursing waiver granted under § 488.54(c) of this chapter.

(4) The hospital has not had a swing-bed approval terminated within the two years previous to application.

(b) *Skilled nursing facility services.* The facility is substantially in compliance with the following skilled nursing facility requirements contained in subpart B of part 483 of this chapter.

(1) Resident rights (§ 483.10(b)(7), (c)(1), (c)(2)(iii), (c)(6), (d), (e)(2), (e)(4), (f)(4)(ii), (f)(4)(iii), (f)(9), (h), (g)(8), (g)(17), and (g)(18) introductory text.

(2) Admission, transfer, and discharge rights (§ 483.5 definition of transfer and discharge, § 483.15(c)(1), (c)(2)(i), (c)(2)(ii), (c)(3), (c)(4), (c)(5), and (c)(7)).

(3) Freedom from abuse, neglect, and exploitation (§ 483.12(a)(1), (a)(2), (a)(3)(i), (a)(3)(ii), (a)(4), (b)(1), (b)(2), (c)).

(4) Patient activities (§ 483.24(c)).

(5) Social services (§ 483.40(d) and 483.70(p)).

(6) Discharge planning (§ 483.20(e)).

(7) Specialized rehabilitative services (§ 483.65).

(8) Dental services (§ 483.55).

[72 FR 60788, Oct. 26, 2007. Redesignated at 79 FR 27155, May 12, 2014, as amended at 81 FR 68847, Oct. 4, 2016; 82 FR 32258, July 13, 2017]

EFFECTIVE DATE NOTE: At 84 FR 51821, Sept. 30, 2019, § 482.58 was amended by revising paragraph (b)(1); removing paragraph (b)(4); redesignating paragraphs (b)(5) through (8) as paragraphs (b)(4) through (7); and revising newly redesignated paragraphs (b)(4), (5), and (7), effective Nov. 29, 2019. For the convenience of the user, the revised text is set forth as follows:

§ 482.58 Special requirements for hospital providers of long-term care services ("swing-beds").

* * * * *

(b) * * *

(1) Resident rights (§ 483.10(b)(7), (c)(1), (c)(2)(iii), (c)(6), (d), (e)(2) and (4), (f)(4)(ii) and (iii), (h), (g)(8) and (17), and (g)(18) introductory text of this chapter).

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(4) Social services (§ 483.40(d) of this chapter).

(5) Discharge summary (§ 483.20(1)).

* * * * *

(7) Dental services (§ 483.55(a)(2), (3), (4), and (5) and (b) of this chapter).

Subpart E—Requirements for Specialty Hospitals

SOURCE: 72 FR 15273, Mar. 30, 2007, unless otherwise noted.

§ 482.60 Special provisions applying to psychiatric hospitals.

Psychiatric hospital must—

(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;

(b) Meet the conditions of participation specified in §§ 482.1 through 482.23 and §§ 482.25 through 482.57;

(c) Maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in § 482.61; and

(d) Meet the staffing requirements specified in § 482.62.

[72 FR 60788, Oct. 26, 2007]

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

(a) *Standard: Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

(1) The identification data must include the patient's legal status.

(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

§ 482.61, Nt.

42 CFR Ch. IV (10–1–19 Edition)

(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(b) *Standard: Psychiatric evaluation.* Each patient must receive a psychiatric evaluation that must—

(1) Be completed within 60 hours of admission;

(2) Include a medical history;

(3) Contain a record of mental status;

(4) Note the onset of illness and the circumstances leading to admission;

(5) Describe attitudes and behavior;

(6) Estimate intellectual functioning, memory functioning, and orientation; and

(7) Include an inventory of the patient's assets in descriptive, not interpretative, fashion.

(c) *Standard: Treatment plan.* (1) Each patient must have an individual comprehensive treatment plan that must be based on an inventory of the patient's strengths and disabilities. The written plan must include—

(i) A substantiated diagnosis;

(ii) Short-term and long-range goals;

(iii) The specific treatment modalities utilized;

(iv) The responsibilities of each member of the treatment team; and

(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

(d) *Standard: Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in § 482.12(c), nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month

thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

(e) *Standard: Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

[72 FR 60788, Oct. 26, 2007]

EFFECTIVE DATE NOTE: At 84 FR 51821, Sept. 30, 2019, § 482.61 was amended by revising paragraph (d), effective Nov. 29, 2019. For the convenience of the user, the revised text is set forth as follows:

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

* * * * *

(d) *Standard: Recording progress.* Progress notes must be recorded by the physicians(s), psychologists, or other licensed independent practitioner(s) responsible for the care of the patient as specified in § 482.12(c); nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

* * * * *

§ 482.62 Condition of participation: Special staff requirements for psychiatric hospitals.

The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

(a) *Standard: Personnel.* The hospital must employ or undertake to provide

adequate numbers of qualified professional, technical, and consultative personnel to:

- (1) Evaluate patients;
- (2) Formulate written individualized, comprehensive treatment plans;
- (3) Provide active treatment measures; and
- (4) Engage in discharge planning.

(b) *Standard: Director of inpatient psychiatric services; medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(1) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(c) *Standard: Availability of medical personnel.* Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic and treatment services are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

(d) *Standard: Nursing services.* The hospital must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

(1) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(2) The staffing pattern must insure the availability of a registered professional nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.

(e) *Standard: Psychological services.* The hospital must provide or have available psychological services to meet the needs of the patients.

(f) *Standard: Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures.

(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a masters degree in social work, at least one staff member must have this qualification.

(2) Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

(g) *Standard: Therapeutic activities.* The hospital must provide a therapeutic activities program.

(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and

§ 482.68

maintaining optimal levels of physical and psychosocial functioning.

(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

[72 FR 60788, Oct. 26, 2007]

§ 482.68 Special requirement for transplant centers.

A transplant center located within a hospital that has a Medicare provider agreement must meet the conditions of participation specified in §§ 482.72 through 482.104 in order to be granted approval from CMS to provide transplant services.

(a) Unless specified otherwise, the conditions of participation at §§ 482.72 through 482.104 apply to heart, heart-lung, intestine, kidney, liver, lung, and pancreas centers.

(b) In addition to meeting the conditions of participation specified in §§ 482.72 through 482.104, a transplant center must also meet the conditions of participation in §§ 482.1 through 482.57, except for § 482.15.

[81 FR 64030, Sept. 16, 2016]

EFFECTIVE DATE NOTE: At 84 FR 51821, Sept. 30, 2019, § 482.68 was amended in the section heading by removing the phrase “transplant centers” and adding in its place the phrase “transplant programs”; and in the introductory text and in paragraph (b) by removing the phrase “transplant center” and adding in its place the phrase “transplant program”, effective Nov. 29, 2019.

§ 482.70 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof. As applied to transplant centers, examples of adverse events include (but are not limited to) serious medical complications or death caused by living donation; unintentional transplantation of organs of mismatched blood types; transplantation of organs to unintended beneficiaries; and unintended transmission of infectious disease to a beneficiary.

End-Stage Renal Disease (ESRD) means that stage of renal impairment

42 CFR Ch. IV (10–1–19 Edition)

that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD Network means all Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Heart-Lung transplant center means a transplant center that is located in a hospital with an existing Medicare-approved heart transplant center and an existing Medicare-approved lung center that performs combined heart-lung transplants.

Intestine transplant center means a Medicare-approved liver transplant center that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants.

Network organization means the administrative governing body to the network and liaison to the Federal government.

Pancreas transplant center means a Medicare-approved kidney transplant center that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

Transplant center means an organ-specific transplant program (as defined in this rule) within a transplant hospital (for example, a hospital's lung transplant program may also be referred to as the hospital's lung transplant center).

Transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant program means a component within a transplant hospital (as defined in this rule) that provides transplantation of a particular type of organ.

EFFECTIVE DATE NOTE: At 84 FR 51821, Sept. 30, 2019, § 482.70 was amended—

a. In the definition of “Adverse event” by removing the phrase “transplant centers” and adding in its place the phrase “transplant programs”;

b. By removing the definition of “Heart-Lung transplant center”;

c. By adding definitions for “Heart-Lung transplant program” and “Intestine transplant program” in alphabetical order;

d. By removing the definition of “Intestine transplant center”;

Centers for Medicare & Medicaid Services, HHS

§ 482.74

- e. By adding a definition for “Intestine transplant program” in alphabetical order;
- f. By removing the definition of “Pancreas transplant center”;
- g. By adding a definition for “Pancreas transplant program” in alphabetical order;
- h. By removing the definition of “Transplant center”;
- i. By revising the definition of “Transplant program”.

The amendments are effective Nov. 29, 2019. For the convenience of the user, the added and revised text is set forth as follows:

§ 482.70 Definitions.

* * * * *

Heart-Lung transplant program means a transplant program that is located in a hospital with an existing Medicare-approved heart transplant program and an existing Medicare-approved lung program that performs combined heart-lung transplants.

Intestine transplant program means a Medicare-approved liver transplant program that performs intestine transplants, combined liver-intestine transplants, or multivisceral transplants.

* * * * *

Pancreas transplant program means a Medicare-approved kidney transplant program that performs pancreas transplants alone or subsequent to a kidney transplant as well as kidney-pancreas transplants.

* * * * *

Transplant program means an organ-specific transplant program within a transplant hospital (as defined in this section).

GENERAL REQUIREMENTS FOR TRANSPLANT CENTERS

§ 482.72 Condition of participation: OPTN membership.

A transplant center must be located in a transplant hospital that is a member of and abides by the rules and requirements of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274). The term “rules and requirements of the OPTN” means those rules and requirements approved by the Secretary pursuant to § 121.4 of this title. No hospital that provides transplantation services shall be deemed to be out of compliance with section 1138(a)(1)(B) of the Act or this section unless the Sec-

retary has given the OPTN formal notice that he or she approves the decision to exclude the transplant hospital from the OPTN and also has notified the transplant hospital in writing.

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.72 was amended by removing the words “transplant center” and adding in their place the words “transplant program”, effective Nov. 29, 2019.

§ 482.74 Condition of participation: Notification to CMS.

(a) A transplant center must notify CMS immediately of any significant changes related to the center's transplant program or changes that could affect its compliance with the conditions of participation. Instances in which CMS should receive information for follow up, as appropriate, include, but are not limited to:

(1) Change in key staff members of the transplant team, such as a change in the individual the transplant center designated to the OPTN as the center's “primary transplant surgeon” or “primary transplant physician;”

(2) Termination of an agreement between the hospital in which the transplant center is located and an OPO for the recovery and receipt of organs as required by section 482.100; and

(3) Inactivation of the transplant center.

(b) Upon receiving notification of significant changes, CMS will follow up with the transplant center as appropriate, including (but not limited to):

(1) Requesting additional information;

(2) Analyzing the information; or

(3) Conducting an on-site review.

[72 FR 15273, Mar. 30, 2007, as amended at 79 FR 27155, May 12, 2014]

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.74 was amended in paragraph (a) introductory text by removing the words “transplant center” and “center's” and adding in their place the words “transplant program” and “hospital's”, respectively; in paragraph (a)(1) by removing the words “transplant center” and “center's” and adding in their place the words “transplant program” and “program's”, respectively; and in paragraphs (a)(2) and (3) and (b) introductory text by removing the words “transplant center” and adding in their place the words “transplant program”, effective Nov. 29, 2019.

§ 482.76

42 CFR Ch. IV (10–1–19 Edition)

§ 482.76 Condition of participation: Pediatric Transplants.

A transplant center that seeks Medicare approval to provide transplantation services to pediatric patients must submit to CMS a request specifically for Medicare approval to perform pediatric transplants using the procedures described at § 488.61 of this chapter.

(a) Except as specified in paragraph (d) of this section, a center requesting Medicare approval to perform pediatric transplants must meet all the conditions of participation at §§ 482.72 through 482.74 and §§ 482.80 through 482.104 with respect to its pediatric patients.

(b) A center that performs 50 percent or more of its transplants in a 12-month period on adult patients must be approved to perform adult transplants in order to be approved to perform pediatric transplants.

(1) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, will result in loss of the center's approval to perform pediatric transplants.

(2) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, may trigger a review of the center's Medicare approval to perform adult transplants.

(c) A center that performs 50 percent or more of its transplants in a 12-month period on pediatric patients must be approved to perform pediatric transplants in order to be approved to perform adult transplants.

(1) Loss of Medicare approval to perform pediatric transplants, whether voluntary or involuntary, will result in loss of the center's approval to perform adult transplants.

(2) Loss of Medicare approval to perform adult transplants, whether voluntary or involuntary, may trigger a review of the center's Medicare approval to perform pediatric transplants.

(3) A center that performs 50 percent or more of its transplants on pediatric patients in a 12-month period is not required to meet the clinical experience requirements prior to its request for approval as a pediatric transplant center.

(d) Instead of meeting all conditions of participation at §§ 482.72 through 482.74 and §§ 482.80 through 482.104, a heart transplant center that wishes to provide transplantation services to pediatric heart patients may be approved to perform pediatric heart transplants by meeting the Omnibus Budget Reconciliation Act of 1987 criteria in section 4009(b) (Pub. L. 100–203), as follows:

(1) The center's pediatric transplant program must be operated jointly by the hospital and another facility that is Medicare-approved;

(2) The unified program shares the same transplant surgeons and quality improvement program (including oversight committee, patient protocol, and patient selection criteria); and

(3) The center demonstrates to the satisfaction of the Secretary that it is able to provide the specialized facilities, services, and personnel that are required by pediatric heart transplant patients.

§ 482.78 Condition of participation: Emergency preparedness for transplant centers.

A transplant center must be included in the emergency preparedness planning and the emergency preparedness program as set forth in § 482.15 for the hospital in which it is located. However, a transplant center is not individually responsible for the emergency preparedness requirements set forth in § 482.15.

(a) *Standard: Policies and procedures.* A transplant center must have policies and procedures that address emergency preparedness. These policies and procedures must be included in the hospital's emergency preparedness program.

(b) *Standard: Protocols with hospital and OPO.* A transplant center must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the transplant center, the hospital in which the transplant center is operated, and the OPO designated by the Secretary, unless the hospital has an approved waiver to work with another OPO, during an emergency.

[81 FR 64030, Sept. 16, 2016]

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.78 was amended in the section heading by removing the words “transplant centers” and adding in their place the words “transplant programs”; and in the introductory text and paragraphs (a) and (b) by removing the words “transplant center” and adding in their place the words “transplant program”, effective Nov. 29, 2019.

TRANSPLANT CENTER DATA SUBMISSION,
CLINICAL EXPERIENCE, AND OUTCOME
REQUIREMENTS

**§ 482.80 Condition of participation:
Data submission, clinical experi-
ence, and outcome requirements for
initial approval of transplant cen-
ters.**

Except as specified in paragraph (d) of this section, and § 488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements to be granted initial approval by CMS.

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of required data on all transplants (deceased and living donor) it has performed. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant beneficiary registration and follow-up, and living donor registration and follow-up.

(b) *Standard: Clinical experience.* To be considered for initial approval, an organ-specific transplant center must generally perform 10 transplants over a 12-month period.

(c) *Standard: Outcome requirements.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. CMS will review adult and pediatric outcomes separately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center’s observed number of patient deaths and graft failures 1-year post-transplant to the center’s expected number of patient deaths and graft failures 1-year post-transplant using the data contained in the most recent Scientific Registry of Transplant Beneficiaries (SRTR) center-specific report.

(2) CMS will not consider a center’s patient and graft survival rates to be acceptable if:

(i) A center’s observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate or expected graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05.

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.85.

(d) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the center.

(2) An intestine transplant center is not required to comply with the outcome performance requirements in paragraph (c) of this section for intestine, combined liver-intestine or multi-visceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for pancreas transplants performed at the center.

(4) A center that is requesting initial Medicare approval to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section prior to its request for approval as a pediatric transplant center.

(5) A kidney transplant center that is not Medicare-approved on the effective date of this rule is required to perform at least 3 transplants over a 12-month period prior to its request for initial approval.

[72 FR 15273, Mar. 30, 2007, as amended at 79 FR 27155, May 12, 2014; 81 FR 79880, Nov. 14, 2016]

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.80 was amended in each paragraph indicated in the following table by

§ 482.82

42 CFR Ch. IV (10–1–19 Edition)

removing the phrase indicated in the third column each time it appears and adding the

reference indicated in the fourth column, effective Nov. 29, 2019:

Section	Paragraphs	Remove	Add
§ 482.80	Section heading	transplant centers	transplant programs.
§ 482.80	Introductory text	transplant centers	transplant programs.
§ 482.80	(a)	transplant center	transplant program.
§ 482.80	(a)	beneficiary	recipient.
§ 482.80	(b)	transplant center	transplant program.
§ 482.80	(c) introductory text	center	program.
§ 482.80	(c)(1)	transplant center's	transplant program's.
§ 482.80	(c)(1)	center-specific report	program-specific report.
§ 482.80	(c)(1)	beneficiaries	recipients.
§ 482.80	(c)(2)	center's	program's.
§ 482.80	(d)(1)	transplant center	transplant program.
§ 482.80	(d)(1)	center	program.
§ 482.80	(d)(2)	transplant center	transplant program.
§ 482.80	(d)(2)	center	program.
§ 482.80	(d)(3)	transplant center	transplant program.
§ 482.80	(d)(3)	center	program.
§ 482.80	(d)(4)	transplant center	transplant program.
§ 482.80	(d)(4)	center	program.
§ 482.80	(d)(5)	transplant center	transplant program.

§ 482.82 Condition of participation: Data submission, clinical experience, and outcome requirements for re-approval of transplant centers.

Except as specified in paragraph (d) of this section, and § 488.61 of this chapter, transplant centers must meet all data submission, clinical experience, and outcome requirements in order to be re-approved.

(a) *Standard: Data submission.* No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of the required data submissions on all transplants (deceased and living donors) performed during the prior 3 years. Required data submissions include, but are not limited to, submission of the appropriate OPTN forms for transplant candidate registration, transplant recipient registration and follow-up, and living donor registration and follow-up.

(b) *Standard: Clinical experience.* To be considered for re-approval, an organ-specific transplant center must generally perform an average of 10 transplants per year during the prior 3 years.

(c) *Standard: Outcome requirements.* CMS will review outcomes for all transplants performed at a center, including outcomes for living donor transplants, if applicable. CMS will review adult and pediatric outcomes sep-

arately when a center requests Medicare approval to perform both adult and pediatric transplants.

(1) CMS will compare each transplant center's observed number of patient deaths and graft failures 1-year post-transplant to the center's expected number of patient deaths and graft failures 1-year post-transplant using data contained in the most recent SRTTR center-specific report.

(2) CMS will not consider a center's patient and graft survival rates to be acceptable if:

(i) A center's observed patient survival rate or observed graft survival rate is lower than its expected patient survival rate and graft survival rate; and

(ii) All three of the following thresholds are crossed over:

(A) The one-sided p-value is less than 0.05,

(B) The number of observed events (patient deaths or graft failures) minus the number of expected events is greater than 3, and

(C) The number of observed events divided by the number of expected events is greater than 1.85.

(d) *Exceptions.* (1) A heart-lung transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section

Centers for Medicare & Medicaid Services, HHS

§ 482.90, Nt.

or the outcome requirements in paragraph (c) of this section for heart-lung transplants performed at the center.

(2) An intestine transplant center is not required to comply with the outcome requirements in paragraph (c) of this section for intestine, combined liver-intestine, and multivisceral transplants performed at the center.

(3) A pancreas transplant center is not required to comply with the clinical experience requirements in paragraph (b) of this section or the outcome requirements in paragraph (c) of this section for pancreas transplants performed at the center.

(4) A center that is approved to perform pediatric transplants is not required to comply with the clinical experience requirements in paragraph (b) of this section to be re-approved.

[72 FR 15273, Mar. 30, 2007, as amended at 79 FR 27155, May 12, 2014; 81 FR 79880, Nov. 14, 2016]

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.82 was removed, effective Nov. 29, 2019.

TRANSPLANT CENTER PROCESS REQUIREMENTS

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, this undesignated center heading was revised to read “Transplant Program Process Requirements”, effective Nov. 29, 2019.

§ 482.90 Condition of participation: Patient and living donor selection.

The transplant center must use written patient selection criteria in determining a patient's suitability for placement on the waiting list or a patient's suitability for transplantation. If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

(a) *Standard: Patient selection.* Patient selection criteria must ensure fair and non-discriminatory distribution of organs.

(1) Prior to placement on the center's waiting list, a prospective transplant candidate must receive a psychosocial evaluation, if possible.

(2) Before a transplant center places a transplant candidate on its waiting list, the candidate's medical record must contain documentation that the candidate's blood type has been determined.

(3) When a patient is placed on a center's waiting list or is selected to receive a transplant, the center must document in the patient's medical record the patient selection criteria used.

(4) A transplant center must provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by a patient or a dialysis facility.

(b) *Standard: Living donor selection.* The living donor selection criteria must be consistent with the general principles of medical ethics. Transplant centers must:

(1) Ensure that a prospective living donor receives a medical and psychosocial evaluation prior to donation,

(2) Document in the living donor's medical records the living donor's suitability for donation, and

(3) Document that the living donor has given informed consent, as required under § 482.102.

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.90 was amended in each paragraph indicated in the following table by removing the phrase indicated in the third column each time it appears and adding the reference indicated in the fourth column, effective Nov. 29, 2019:

Section	Paragraphs	Remove	Add
§ 482.90	Introductory text	transplant center	transplant program.
§ 482.90	Introductory text	center	program.
§ 482.90	(a)(1)	center's waiting list	program's waiting list.
§ 482.90	(a)(2)	transplant center	transplant program.
§ 482.90	(a)(3)	center's waiting list	program's waiting list.
§ 482.90	(a)(4)	transplant center	transplant program.
§ 482.90	(b) introductory text	Transplant centers	Transplant programs.

§ 482.92 Condition of participation: Organ recovery and receipt.

Transplant centers must have written protocols for validation of donor-beneficiary blood type and other vital data for the deceased organ recovery, organ receipt, and living donor organ transplantation processes. The transplanting surgeon at the transplant center is responsible for ensuring the medical suitability of donor organs for transplantation into the intended beneficiary.

(a) *Standard: Organ receipt.* After an organ arrives at a transplant center, prior to transplantation, the transplanting surgeon and another licensed health care professional must verify that the donor's blood type and other vital data are compatible with transplantation of the intended beneficiary.

(b) *Standard: Living donor transplantation.* If a center performs living donor transplants, the transplanting surgeon and another licensed health care professional at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended beneficiary immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the beneficiary's organ(s).

[51 FR 22042, June 17, 1986, as amended at 77 FR 29076, May 16, 2012]

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.92 was amended in each paragraph indicated in the following table by removing the phrase indicated in the third column each time it appears and adding the reference indicated in the fourth column, effective Nov. 29, 2019:

Section	Paragraphs	Remove	Add
§ 482.92	Introductory text	donor-beneficiary	donor-recipient.
§ 482.92	Introductory text	beneficiary	recipient.
§ 482.92	Introductory text	Transplant centers	Transplant programs.
§ 482.92	Introductory text	transplant center	transplant program.
§ 482.92	(a)	transplant center	transplant program.
§ 482.92	(a)	beneficiary	recipient.
§ 482.92	(b)	center	program.
§ 482.92	(b)	beneficiary	recipient.
§ 482.92	(b)	beneficiary's	recipient's.

§ 482.94 Condition of participation: Patient and living donor management.

Transplant centers must have written patient management policies for the transplant and discharge phases of transplantation. If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation.

(a) *Standard: Patient and living donor care.* The transplant center's patient and donor management policies must ensure that:

(1) Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation; and

(2) If a center performs living donor transplants, each living donor is under the care of a multidisciplinary patient care team coordinated by a physician

throughout the donor evaluation, donation, and discharge phases of donation.

(b) *Standard: Waiting list management.* Transplant centers must keep their waiting lists up to date on an ongoing basis, including:

(1) Updating of waiting list patients' clinical information;

(2) Removing patients from the center's waiting list if a patient receives a transplant or dies, or if there is any other reason the patient should no longer be on a center's waiting list; and

(3) Notifying the OPTN no later than 24 hours after a patient's removal from the center's waiting list.

(c) *Standard: Patient records.* Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waiting list and who is admitted for organ transplantation.

(1) For each patient who receives an evaluation for placement on a center's

Centers for Medicare & Medicaid Services, HHS

§ 482.94, Nt.

waiting list, the center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) has been informed of his or her transplant status, including notification of:

- (i) The patient's placement on the center's waiting list;
- (ii) The center's decision not to place the patient on its waiting list; or
- (iii) The center's inability to make a determination regarding the patient's placement on its waiting list because further clinical testing or documentation is needed.

(2) If a patient on the waiting list is removed from the waiting list for any reason other than death or transplantation, the transplant center must document in the patient's record that the patient (and in the case of a kidney patient, the patient's usual dialysis facility) was notified no later than 10 days after the date the patient was removed from the waiting list.

(3) In the case of patients admitted for organ transplants, transplant centers must maintain written records of:

- (i) Multidisciplinary patient care planning during the transplant period; and
- (ii) Multidisciplinary discharge planning for post-transplant care.

(d) *Standard: Social services.* The transplant center must make social services available, furnished by qualified social workers, to transplant patients, living donors, and their fami-

lies. A qualified social worker is an individual who meets licensing requirements in the State in which he or she practices; and

(1) Completed a course of study with specialization in clinical practice and holds a master's degree from a graduate school of social work accredited by the Council on Social Work Education; or

(2) Is working as a social worker in a transplant center as of the effective date of this final rule and has served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under (d)(1) of this paragraph.

(e) *Standard: Nutritional services.* Transplant centers must make nutritional assessments and diet counseling services, furnished by a qualified dietitian, available to all transplant patients and living donors. A qualified dietitian is an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration.

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.94 was amended in each paragraph indicated in the following table by removing the phrase indicated in the third column each time it appears and adding the reference indicated in the fourth column, effective Nov. 29, 2019:

Section	Paragraphs	Remove	Add
§ 482.94	Introductory text	Transplant centers	Transplant programs.
§ 482.94	Introductory text	transplant center	transplant programs.
§ 482.94	Introductory text	the center also	the program also.
§ 482.94	(a) introductory text	transplant center's	transplant program's.
§ 482.94	(a)(2)	center	program.
§ 482.94	(b) introductory text	Transplant centers	Transplant programs.
§ 482.94	(b)(2)	center's	program's.
§ 482.94	(b)(3)	center's	program's.
§ 482.94	(c) introductory text	Transplant centers	Transplant programs.
§ 482.94	(c) introductory text	center's waiting list	program's waiting list.
§ 482.94	(c)(1) introductory text	center's waiting list	program's waiting list.
§ 482.94	(c)(1) introductory text	center	program.
§ 482.94	(c)(1)(i)	center's waiting list	program's waiting list.
§ 482.94	(c)(1)(ii)	center's	program's.
§ 482.94	(c)(1)(iii)	center's	program's.
§ 482.94	(c)(2)	transplant center	transplant program.
§ 482.94	(c)(3) introductory text	transplant centers	transplant programs.
§ 482.94	(d) introductory text	transplant center	transplant program.
§ 482.94	(d)(2)	transplant center	transplant program.
§ 482.94	(e)	Transplant centers	Transplant programs.

§ 482.96 Condition of participation: Quality assessment and performance improvement (QAPI).

Transplant centers must develop, implement, and maintain a written, comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement.

(a) *Standard: Components of a QAPI program.* The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and beneficiary matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights. The transplant center must take actions that result in per-

formance improvements and track performance to ensure that improvements are sustained.

(b) *Standard: Adverse events.* A transplant center must establish and implement written policies to address and document adverse events that occur during any phase of an organ transplantation case.

(1) The policies must address, at a minimum, the process for the identification, reporting, analysis, and prevention of adverse events.

(2) The transplant center must conduct a thorough analysis of and document any adverse event and must utilize the analysis to effect changes in the transplant center's policies and practices to prevent repeat incidents.

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.96 was amended in each paragraph indicated in the following table by removing the phrase indicated in the third column each time it appears and adding the reference indicated in the fourth column, effective Nov. 29, 2019:

Section	Paragraphs	Remove	Add
§ 482.96	Introductory text	Transplant centers	Transplant programs.
§ 482.96	(a)	transplant center's	transplant program's.
§ 482.96	(a)	beneficiary	recipient.
§ 482.96	(a)	transplant center	transplant program.
§ 482.96	(b) introductory text	transplant center	transplant program.
§ 482.96	(b)(2)	transplant center	transplant program.
§ 482.96	(b)(2)	transplant center's	transplant program's.

§ 482.98 Condition of participation: Human resources.

The transplant center must ensure that all individuals who provide services and/or supervise services at the center, including individuals furnishing services under contract or arrangement, are qualified to provide or supervise such services.

(a) *Standard: Director of a transplant center.* The transplant center must be under the general supervision of a qualified transplant surgeon or a qualified physician-director. The director of a transplant center need not serve full-time and may also serve as a center's primary transplant surgeon or transplant physician in accordance with § 482.98(b). The director is responsible for planning, organizing, conducting, and directing the transplant center and

must devote sufficient time to carry out these responsibilities, which include but are not limited to the following:

(1) Coordinating with the hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.

(2) Ensuring that tissue typing and organ procurement services are available.

(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with § 482.98(b).

(b) *Standard: Transplant surgeon and physician.* The transplant center must

Centers for Medicare & Medicaid Services, HHS

§ 482.98, Nt.

identify to the OPTN a primary transplant surgeon and a transplant physician with the appropriate training and experience to provide transplantation services, who are immediately available to provide transplantation services when an organ is offered for transplantation.

(1) The transplant surgeon is responsible for providing surgical services related to transplantation.

(2) The transplant physician is responsible for providing and coordinating transplantation care.

(c) *Standard: Clinical transplant coordinator.* The transplant center must have a clinical transplant coordinator to ensure the continuity of care of patients and living donors during the pre-transplant, transplant, and discharge phases of transplantation and the donor evaluation, donation, and discharge phases of donation. The clinical transplant coordinator must be a registered nurse or clinician licensed by the State in which the clinical transplant coordinator practices, who has experience and knowledge of transplantation and living donation issues. The clinical transplant coordinator's responsibilities must include, but are not limited to, the following:

(1) Ensuring the coordination of the clinical aspects of transplant patient and living donor care; and

(2) Acting as a liaison between a kidney transplant center and dialysis facilities, as applicable.

(d) *Standard: Independent living donor advocate or living donor advocate team.* The transplant center that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.

(1) The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.

(2) The independent living donor advocate or living donor advocate team must demonstrate:

(i) Knowledge of living organ donation, transplantation, medical ethics, and informed consent; and

(ii) Understanding of the potential impact of family and other external pressures on the prospective living donor's decision whether to donate and the ability to discuss these issues with the donor.

(3) The independent living donor advocate or living donor advocate team is responsible for:

(i) Representing and advising the donor;

(ii) Protecting and promoting the interests of the donor; and

(iii) Respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.

(e) *Standard: Transplant team.* The transplant center must identify a multidisciplinary transplant team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.

(f) *Standard: Resource commitment.* The transplant center must demonstrate availability of expertise in internal medicine, surgery, anesthesiology, immunology, infectious disease control, pathology, radiology, blood banking, and patient education as related to the provision of transplantation services.

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.98 was amended in each paragraph indicated in the following table by removing the phrase indicated in the third column each time it appears and adding the reference indicated in the fourth column, effective Nov. 29, 2019:

Section	Paragraphs	Remove	Add
§ 482.98	Introductory text	transplant center	transplant program.
§ 482.98	Introductory text	the center	the program.
§ 482.98	(a) heading and introductory text	transplant center	transplant program.
§ 482.98	(a) introductory text	center's	program's.
§ 482.98	(a)(1)	transplant center	transplant program.
§ 482.98	(b) introductory text	transplant center	transplant program.
§ 482.98	(c) introductory text	transplant center	transplant program.
§ 482.98	(c)(2)	transplant center	transplant program.

Section	Paragraphs	Remove	Add
§ 482.98	(d) introductory text	transplant center	transplant program.
§ 482.98	(d) heading	living donor advocate team	independent living donor advocate team.
§ 482.98	(d)(1)	living donor advocate	independent living donor advocate.
§ 482.98	(d)(2) introductory text	living donor advocate team	independent living donor advocate team.
§ 482.98	(d)(3) introductory text	living donor advocate team	independent living donor advocate team.
§ 482.98	(e)	transplant center	transplant program.
§ 482.98	(f)	transplant center	transplant program.

§ 482.100 Condition of participation: Organ procurement.

The transplant center must ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.100 was amended by removing the words “transplant center” and adding in their place the words “transplant program”, effective Nov. 29, 2019.

§ 482.102 Condition of participation: Patient and living donor rights.

In addition to meeting the condition of participation “Patients rights” requirements at § 482.13, the transplant center must protect and promote each transplant patient’s and living donor’s rights.

(a) *Standard: Informed consent for transplant patients.* Transplant centers must implement written transplant patient informed consent policies that inform each patient of:

- (1) The evaluation process;
- (2) The surgical procedure;
- (3) Alternative treatments;
- (4) Potential medical or psychosocial risks;
- (5) National and transplant center-specific outcomes, from the most recent SRTR center-specific report, including (but not limited to) the transplant center’s observed and expected 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center;
- (6) Organ donor risk factors that could affect the success of the graft or

the health of the patient, including, but not limited to, the donor’s history, condition or age of the organs used, or the patient’s potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor;

(7) His or her right to refuse transplantation; and

(8) The fact that if his or her transplant is not provided in a Medicare-approved transplant center it could affect the transplant beneficiary’s ability to have his or her immunosuppressive drugs paid for under Medicare Part B.

(b) *Standard: Informed consent for living donors.* Transplant centers must implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Transplant centers must ensure that the prospective living donor is fully informed about the following:

(1) The fact that communication between the donor and the transplant center will remain confidential, in accordance with the requirements at 45 CFR parts 160 and 164.

(2) The evaluation process;

(3) The surgical procedure, including post-operative treatment;

(4) The availability of alternative treatments for the transplant beneficiary;

(5) The potential medical or psychosocial risks to the donor;

(6) The national and transplant center-specific outcomes for beneficiaries, and the national and center-specific outcomes for living donors, as data are available;

(7) The possibility that future health problems related to the donation may

Centers for Medicare & Medicaid Services, HHS

§ 482.102, Nt.

not be covered by the donor's insurance and that the donor's ability to obtain health, disability, or life insurance may be affected;

(8) The donor's right to opt out of donation at any time during the donation process; and

(9) The fact that if a transplant is not provided in a Medicare-approved transplant center it could affect the transplant beneficiary's ability to have his or her immunosuppressive drugs paid for under Medicare Part B.

(c) *Standard: Notification to patients.* Transplant centers must notify patients placed on the center's waiting list of information about the center that could impact the patient's ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team.

(1) A transplant center served by a single transplant surgeon or physician must inform patients placed on the center's waiting list of:

(i) The potential unavailability of the transplant surgeon or physician; and

(ii) Whether the center has a mechanism to provide an alternate transplant surgeon or transplant physician.

(2) At least 30 days before a center's Medicare approval is terminated,

whether voluntarily or involuntarily, the center must:

(i) Inform patients on the center's waiting list and provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list; and

(ii) Inform Medicare beneficiaries on the center's waiting list that Medicare will no longer pay for transplants performed at the center after the effective date of the center's termination of approval.

(3) As soon as possible prior to a transplant center's voluntary inactivation, the center must inform patients on the center's waiting list and, as directed by the Secretary, provide assistance to waiting list patients who choose to transfer to the waiting list of another Medicare-approved transplant center without loss of time accrued on the waiting list.

EFFECTIVE DATE NOTES: 1. At 84 FR 51822, Sept. 30, 2019, § 482.102 was amended in each paragraph indicated in the following table by removing the phrase indicated in the third column each time it appears and adding the reference indicated in the fourth column, effective Nov. 29, 2019:

Section	Paragraphs	Remove	Add
§ 482.102	Introductory text	transplant center	transplant program.
§ 482.102	(a) introductory text	Transplant centers	Transplant programs.
§ 482.102	(a)(8)	transplant center	transplant program.
§ 482.102	(a)(8)	beneficiary's	recipient's.
§ 482.102	(b) introductory text	Transplant centers	Transplant programs.
§ 482.102	(b)(1)	transplant center	transplant program.
§ 482.102	(b)(4)	beneficiary	recipient.
§ 482.102	(b)(6)	transplant center-specific	transplant program-specific.
§ 482.102	(b)(6)	beneficiaries	recipients.
§ 482.102	(b)(6)	center-specific outcomes	transplant-specific outcomes.
§ 482.102	(b)(9)	transplant center	transplant program.
§ 482.102	(b)(9)	beneficiary's	recipient's.
§ 482.102	(c) introductory text	Transplant centers	Transplant programs.
§ 482.102	(c) introductory text	center's	program's.
§ 482.102	(c) introductory text	center	program.
§ 482.102	(c)(1) introductory text	transplant center	transplant program.
§ 482.102	(c)(1) introductory text	center's waiting list	program's waiting list.
§ 482.102	(c)(2) introductory text	center's Medicare approval	program's Medicare approval.
§ 482.102	(c)(2)(i)	center's waiting list	program's waiting list.
§ 482.102	(c)(2)(i)	transplant center	transplant program.
§ 482.102	(c)(2)(ii)	beneficiaries	recipients.
§ 482.102	(c)(2)(ii)	center's waiting list	program's waiting list.
§ 482.102	(c)(2)(ii)	the center	the program.
§ 482.102	(c)(2)(ii)	center's termination of approval	program's termination of approval.
§ 482.102	(c)(3)	transplant center's	transplant program's.
§ 482.102	(c)(3)	the center	the program.
§ 482.102	(c)(3)	center's waiting list	program's waiting list.
§ 482.102	(c)(3)	transplant center	transplant program.

§ 482.104

EFFECTIVE DATE NOTES: 2. At 84 FR 51823, Sept. 30, 2019, § 482.102 was further amended by revising paragraph (a)(5), effective Nov. 29, 2019. For the convenience of the user, the added and revised text is set forth as follows:

§ 482.102 Condition of participation: Patient and living donor rights.

* * * * *

(a) * * *

(5) National and transplant program-specific outcomes, from the most recent SRTR program-specific report, including (but not limited to) the transplant program's observed and expected 1-year patient and graft survival, and national 1-year patient and graft survival;

* * * * *

§ 482.104 Condition of participation: Additional requirements for kidney transplant centers.

(a) *Standard: End stage renal disease (ESRD) services.* Kidney transplant centers must directly furnish transplantation and other medical and surgical specialty services required for the care of ESRD patients. A kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.

(b) *Standard: Dialysis services.* Kidney transplant centers must furnish inpatient dialysis services directly or under arrangement.

(c) *Standard: Participation in network activities.* Kidney transplant centers must cooperate with the ESRD Network designated for their geographic area, in fulfilling the terms of the Network's current statement of work.

EFFECTIVE DATE NOTE: At 84 FR 51822, Sept. 30, 2019, § 482.104 was amended by removing the words "transplant center" and "transplant centers" in each place they appear and adding in their place the words "transplant program" and "transplant programs", respectively, effective Nov. 29, 2019.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

Subpart A [Reserved]

42 CFR Ch. IV (10–1–19 Edition)

Subpart B—Requirements for Long Term Care Facilities

Sec.

- 483.1 Basis and scope.
- 483.5 Definitions.
- 483.10 Resident rights.
- 483.12 Freedom from abuse, neglect, and exploitation.
- 483.15 Admission, transfer, and discharge rights.
- 483.20 Resident assessment.
- 483.21 Comprehensive person-centered care planning.
- 483.24 Quality of life.
- 483.25 Quality of care.
- 483.30 Physician services.
- 483.35 Nursing services.
- 483.40 Behavioral health services.
- 483.45 Pharmacy services.
- 483.50 Laboratory, radiology, and other diagnostic services.
- 483.55 Dental services.
- 483.60 Food and nutrition services.
- 483.65 Specialized rehabilitative services.
- 483.70 Administration.
- 483.73 Emergency preparedness.
- 483.75 Quality assurance and performance improvement.
- 483.80 Infection control.
- 483.85 Compliance and ethics program.
- 483.90 Physical environment.
- 483.95 Training requirements.

Subpart C—Preadmission Screening and Annual Review of Mentally Ill and Mentally Retarded Individuals

- 483.100 Basis.
- 483.102 Applicability and definitions.
- 483.104 State plan requirement.
- 483.106 Basic rule.
- 483.108 Relationship of PASARR to other Medicaid processes.
- 483.110 Out-of-State arrangements.
- 483.112 Preadmission screening of applicants for admission to NFs.
- 483.114 Annual review of NF residents.
- 483.116 Residents and applicants determined to require NF level of services.
- 483.118 Residents and applicants determined not to require NF level of services.
- 483.120 Specialized services.
- 483.122 FFP for NF services.
- 483.124 FFP for specialized services.
- 483.126 Appropriate placement.
- 483.128 PASARR evaluation criteria.
- 483.130 PASARR determination criteria.
- 483.132 Evaluating the need for NF services and NF level of care (PASARR/NF).
- 483.134 Evaluating whether an individual with mental illness requires specialized services (PASARR/MI).
- 483.136 Evaluating whether an individual with intellectual disability requires specialized services (PASARR/IID).